

# Study: California's proposal to manufacture insulin could curb prices, improve public health

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A new paper co-written by a University of Illinois Urbana-Champaign legal scholar argues that the state of California's proposal to manufacture

and distribute insulin at cost could be a game-changer for curbing out-of-control price increases on insulin and a boon to public health.

Reducing the price of [insulin](#)—a life-saving medication used by more than 7 million Americans—through California's CalRx Biosimilar Insulin Initiative could be one of the most important and politically relevant wins for [drug](#) policy in decades, said Jacob S. Sherkow, a professor of law and of medicine and an affiliate of the Carl R. Woese Institute for Genomic Biology at Illinois.

"Previous efforts to reduce the prices of the most popular types of insulin, including attempts by states to put price pressure on [drug manufacturers](#), have either been struck down by legal challenges or just been plain ineffective," Sherkow said. "But the CalRx Initiative may offer a path forward for states looking to curb prescription drug prices."

Sherkow's co-authors are Eli Y. Adashi of Brown University and I. Glenn Cohen of Harvard Law School.

CalRx seeks to lower the price of insulin by having the state of California manufacture the drug in a state-owned and managed facility or in partnership with a pharmaceutical contractor. Because the state is manufacturing the drug, it can set its own prices, "which means it could, ideally, set the price of insulin far below the current market prices," Sherkow said.

"High-priced insulin has exacerbated the health of many Americans," he said. "It leads to rationing, which has been found to increase the risk of stroke, [heart attack](#), heart failure and end-stage renal disease among diabetics."

According to the paper, the current market price is around \$300 per vial of insulin. If CalRx were to sell insulin at cost, "it's been estimated that

uninsured patients could save as much as \$4,000 per year, not to mention all the [health benefits](#) associated with not having to ration medication," Sherkow said.

But because neither California nor any other state has experience in making its own generic drugs for sale, it's a proposal that's fraught with several potential legal and logistical challenges, Sherkow said.

"The biggest hurdle is regulatory: the state of California needs to obtain FDA approval to manufacture and market its drug," he said. "This has been a pointed source of criticism of CalRx, especially since neither California nor any other state has ever attempted to manufacture its own drugs, let alone have one approved for marketing by the FDA."

Another potential hurdle is the need for sufficient continuous funding via the often-contentious process of state budgeting.

"Like any other drug, the manufacturing of CalRx-branded insulin is not only a function of the cost of raw materials, but also of facility maintenance, personnel, cleaning, documentation and legal expenses," Sherkow said. "This potential lack of an ironclad guarantee of future funding is a political problem if a new California governor, especially one facing a budget crunch, cuts CalRx's budget as if it were any other line-item in the state budget."

"It also has the potential for a backlash from the larger players in the insulin market, which means CalRX wouldn't be immune to political lobbying from pharmaceutical manufacturers or other forms of regulatory gamesmanship."

But if successful, turning the Golden State into a drug manufacturer would be a novel and historic health policy victory, Sherkow said.

"The policy implications are enormous," he said. "If CalRx were to succeed, it could serve as a model for drug manufacturing beyond just insulin. It could address gaps in drug shortages, which is an under-the-radar problem in [drug policy](#), especially where the drugs serve small patient populations or drugs that are cost-prohibitive for patients."

The model also could be used to sell prescription drugs where the [public health](#) benefit is high but [insurance coverage](#) is limited, such as PrEP for HIV prevention for uninsured individuals who don't qualify for other federal coverage programs, Sherkow said.

"A state-run manufacturer also could produce medications such as contraceptives that are generally available but perhaps aren't covered by employer insurance programs for religious reasons," he said.

And the market for CalRx insulin need not be confined to Californians. CalRx could presumably sell it throughout the country, yielding economies-of-scale effects on price and competition, Sherkow said.

"If CalRx ultimately succeeds, it could stand as an example of government at its best: smoothing market inefficiencies while taking care of its neediest citizens," he said.

The paper was published in the *Journal of the American Medical Association (JAMA)*.

**More information:** Jacob S. Sherkow et al, Assessing—and Extending—California's Insulin Manufacturing Initiative, *JAMA* (2023). [DOI: 10.1001/jama.2023.0013](https://doi.org/10.1001/jama.2023.0013)

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